

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

INSTRUCTIONS FOR APPLICANTS

Early Translational Research Awards RFA R-17.1-ETRA

FY 2017

Fiscal Year Award Period September 1, 2016 - August 31, 2017

TABLE OF CONTENTS

1. INTRODUCTION	4
2. SUMMARY INSTRUCTIONS	4
3. APPLICATION SUBMISSION DEADLINE	
4. APPLICATION PREPARATION AND SUBMISSION PROCESS	5
5. APPLICATION SIGNING OFFICIAL (ASO)	
6. GRANTS CONTRACT/OFFICE OF SPONSORED PROJECTS OFFICIAL	5
7. USER REGISTRATION AND/OR LOGIN	6
8. STARTING A NEW APPLICATION	6
9. STATUS DISPLAY	7
9.1. Tab Status	7
9.2. APPLICATION STATUS	8
10. TAB: SUMMARY	8
11. TAB 1: CONTACTS	
12. TAB 2: APPLICATION INFORMATION	
13. TAB 3: COLLABORATORS & CONFLICTS OF INTEREST	12
14. TAB 4: REQUIRED DOCUMENTS	12
15. TAB 5: BUDGET	15
15.1. SENIOR/KEY PERSON & OTHER PERSONNEL (USE WEB FORM PROVIDED)	
15.2. DETAILED BUDGET FOR YEAR 1 (USE TEXT BOXES/WEB FORM PROVIDED)	
15.3. BUDGET FOR ENTIRE PROPOSED PERIOD OF PERFORMANCE	17
15.4. BUDGET JUSTIFICATION	
15.5. SALARY CAP	
16. TAB 6: FINAL REVIEW & SUBMIT	18
17. PROVIDED TEMPLATES	
18. VERTEBRATE ANIMALS/HUMAN BIOLOGICAL SAMPLES	19
19. FORMATTING INSTRUCTIONS	
20. CONTACT INFORMATION	21
20.1. HelpDesk	21
20.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	
APPENDIX 1: DESCRIPTION OF RESEARCH AREAS	22
APPENDIX 2: PROGRAM FOCUS - DEFINITIONS OF CANCER RESEARCH	
TVPES	23

VERSION HISTORY

Rev 03/21/16 Release of Instructions for Applicants

1. INTRODUCTION

The Cancer Prevention and Research Institute of Texas (CPRIT) Application Receipt System (CARS) provides a means for the research community in Texas (ie, Principal Investigators [PIs] and Application Signing Officials [ASOs]) to respond to CPRIT funding opportunities electronically over the Internet through a secure connection. This document provides instructions and guidance to applicants on how to successfully submit an application in response to CPRIT's Request for Applications (RFA) for Early Translational Research Awards (RFA R-17.1-ETRA). Applications may be submitted from March 21, 2016, through May 19, 2016.

2. SUMMARY INSTRUCTIONS

- **Technical Support:** Applicants are strongly advised to carefully read this document in its entirety before starting an application. The CPRIT HelpDesk (section 20.1) is available to answer technical questions and guide applicants with application submission. This *Instructions* document will be updated as necessary. Revisions will be listed in the *Revision History*.
- **Document Format for Uploaded Files:** Use Portable Document Format (PDF) only.
 - Do NOT password protect documents.
 - o Do NOT submit documents that are bound together in a single PDF package.
- Font Type/Size: Arial (11 point), Calibri (11 point), or Times New Roman (12 point).
- **Page Format:** Single spacing, 0.75 inch margins in all directions.
- **Templates:** Templates are provided for biographical sketches (biosketches), Competitive Landscape/Intellectual Property, and current and pending support. NIH-style biographical sketches can be used if desired.
- **Competitive Landscape:** A plan detailing the Competitive Landscape/Intellectual Property is required.

• Submission Process:

- The applicant completes/finalizes all sections and forwards it to the organization's
 ASO for review and final submission to CPRIT.
- The application must be <u>submitted by the ASO</u> on or before May 19, 2016, 3 PM central time.

• **Note:** CARS will be unavailable the third Thursday of each month between 7 PM and 9 PM central time for routine system maintenance.

• Tab Finalization and Reset

- o Application information saved "as draft" can be edited at a later time.
- Once application information is "finalized for ASO approval," it can be edited only after the ASO resets the section to draft at the request of the applicant.

3. APPLICATION SUBMISSION DEADLINE

The application must be submitted on or before May 19, 2016, 3 PM central time.

4. APPLICATION PREPARATION AND SUBMISSION PROCESS

- The applicant completes/finalizes a series of numbered tabs of the application.
- Finalized tabs can be reset by the ASO.
- Once all tabs are finalized, the ASO reviews, approves, and submits the application to CPRIT.

5. APPLICATION SIGNING OFFICIAL

The ASO is an individual authorized to submit an application on behalf of an organization. An ASO is required on the application and <u>must</u> be identified by the PI.

As the organization's representative, the ASO is required to review the tabs finalized by the PI and subsequently submit the application. Only the ASO is authorized to officially submit the application to CPRIT. The ASO can reset PI-finalized tabs to draft at the request of the PI.

6. GRANTS CONTRACT/OFFICE OF SPONSORED PROJECTS OFFICIAL

The Grants Contract/Office of Sponsored Projects Official is the individual who will manage the grant if an award is made. This individual <u>must</u> be identified for the application. Either the PI or the ASO can assign an individual to this role.

7. USER REGISTRATION AND/OR LOGIN

Applicants begin the application process by registering or logging into CARS at https://CPRITGrants.org. New applicants should remember to set up both an applicant account and an ASO account at this time. Upon successful login to the system, applicants will be presented with the *My Applications* page shown below. All previously submitted applications by the user are listed on this page. After initial registration or after login, all users are encouraged to complete/verify the information under the *My Profile* link on the top left of this screen. A biosketch is required for the PI and the Co-Principal Investigator (Co-PI), if applicable.



8. STARTING A NEW APPLICATION

New applications can be started in 1 of 2 ways:

- i. My Applications (this is the default page after login) → click Start New Application →
 FY 2017 Research Programs → select Early Translational Research Awards → click
 New Application, or
- ii. Current Funding Opportunities → click FY 2017 Research Programs → select Early

 Translational Research Awards → click Start New Application.

Upon starting a new application, applicants are required to enter the title of the application (160-character limit, including spaces; can be edited later) and select the submitter role. Do NOT use

symbols or special characters (eg, Greek letters, bullets)—these will not be transmitted correctly. Once this step is completed, applicants will be directed to the summary page.

Applicants are advised to carefully read the information on the summary page before moving on to the numbered tabs.

- Tab 1 (*Contacts*) **must** be completed/finalized prior to Tab 3 (*Collaborators & COIs*).
- Tab 2 (*Application Information*) **must** be completed/finalized prior to Tab 5 (*Budget*).

Other tabs may be completed in any order. All tabs must be successfully completed/finalized by the PI before the ASO can review, approve, and successfully submit the application.

9. STATUS DISPLAY

9.1. Tab Status

The status of each tab is displayed under the row of numbered tabs. The figure below is an example of the status of Tab 1.



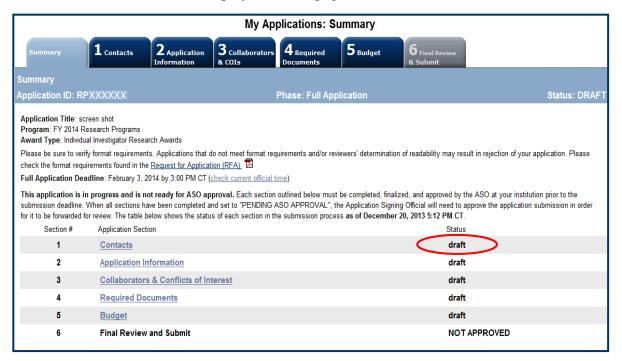
Status	Status Definition	
DRAFT	The tab is being prepared by the applicant.	
PENDING ASO APPROVAL	The tab has been finalized by the applicant. When all tabs are finalized and reflect this status, the ASO will receive email notification stating that the application can be reviewed/submitted. The applicant is included on this notification.	
ASO APPROVED AND SUBMITTED	The ASO has reviewed, approved, and submitted the application to CPRIT. Once the application has been submitted by the ASO, the PI is notified via email.	

Application Status 9.2.

The status displayed under the row of numbered tabs on the Summary tab indicates the status of the application (as indicated in the figure above).

10. **TAB: SUMMARY**

The status of each tab is also displayed on this page. Status definitions are described below.



Section	Status	Status Definition	
	DRAFT	The tab is being prepared by the applicant.	
1-5	PENDING ASO APPROVAL	The tab has been finalized by the applicant. When all tabs are finalized and reflect this status, the ASO will receive email notification that the application can be reviewed/submitted. The applicant is included on this notification.	
6	NOT APPROVED	The application has not been approved/submitted by the ASO.	
	PENDING	All tabs have been finalized by the applicant and reflect the status "pending ASO approval." At this point, the application is awaiting ASO approval and subsequent submission.	

NOTE: As stated in the preceding section, the status displayed under the row of numbered tabs on this page indicates the status of the entire application.

CPRIT

11. TAB 1: CONTACTS

- **Principal Investigator:** Verify information for the PI; update as necessary.
- **Co-Principal Investigator (Optional):** If desired, <u>one</u> Co-PI may be designated on an Early Translational Research Award application. To designate a Co-PI, do the following:
 - Click the *Search for Co-Principal Investigator* button.
 - o Enter information and click the Search Contacts button.
 - If the individual is listed on the subsequent search results page, that individual may be added to the application via the *Add Contact* link.
 - o If the individual is not listed, different search criteria may be used (eg, using the last name only, spelling variations). Alternatively, invite the individual to register in CARS and be part of the application by clicking the *Send Them an Invitation* link. On the subsequent page, complete the fields and click the *Send Invitation* button. When this individual joins the application as a Co-PI, his/her information will be listed in the appropriate section of the tab.
 - o Change or remove an individual by clicking the appropriate button.
- **Alternate Submitter (Optional):** If an alternate submitter is to be designated on the application by the PI, click the *Search for Alternate Submitter* button. Follow the search guidelines above.
- Application Signing Official (Required): An ASO <u>must</u> be listed in order to complete/finalize this tab. Click the *Search for Application Signing Official* button.
 Follow the search guidelines above.
- Alternate Application Signing Official (Optional): This individual can only be assigned by the ASO. Follow the search guidelines above.
- Grants Contract/Office of Sponsored Projects Official (Required): A Grants
 Contract/Office of Sponsored Projects Official <u>must</u> be listed in order to
 complete/finalize this tab. This individual can be assigned by the PI or the ASO. Follow
 the search guidelines above.

When all information is entered, click the *Finalize Contacts* Section button. Note that this tab cannot be finalized until the 3 required fields of this section (namely, "Principal Investigator," "Application Signing Official," and "Grants Contract/Office of Sponsored Projects Official")

have been completed. PI information is entered automatically; an ASO must be identified and added by the PI. The Grants Contract/Office of Sponsored Projects Official may be identified and added by the PI or the ASO.

12. TAB 2: APPLICATION INFORMATION

• Application Identification

- Award Mechanism: Verify the listed award mechanism. Note that the award mechanism cannot be changed.
- Application Type: Verify application type (drop list defaults to *New Application*).
- o **Application Title:** The application title is stated. Edit, if necessary.

• Project Information

- Contract Start Date (m/d/yyyy): The contract start date of 12/1/2016 is prepopulated for all applications.
- **Proposed End Date:** (m/d/yyyy): Enter the proposed end date for the program (a date between 1 and 3 years).
- Entity Fiscal Year End Date (mm/dd/yyyy): Should be completed and/or verified by the ASO. Please enter your company's fiscal year end date for the current calendar year. Example: If your company's fiscal year ends on September 30th each year, please enter 9/30/2016. This date <u>must</u> be confirmed by your ASO.

• Application Classification:

- Research Area: Select the research area that best describes the proposed work.
 Please refer to <u>Appendix 1</u> for a detailed description of each research area.
- Program Focus: Select the focus of the proposed work. Please refer to <u>Appendix</u>
 for definition of cancer research types.
- Cancer Site Addressed: Select the cancer site(s) that will be addressed during the proposed project. The selection of cancer sites in this section assists CPRIT with reporting on cancer research that is being performed. If the proposed project relates to all cancer types or focuses on general cancer research, select "All Sites" from the list. If the proposed project focuses on multiple cancer sites, but not all sites, please select only the sites for which actual work will be performed.

- Vertebrate Animals: Indicate whether vertebrate animals will be used.
- Biologic/Anatomic Substances: Indicate whether cadavers will be used. In addition, specify the use of human anatomical substances. If human anatomical substances will be used, specify if the substances are traceable to specific donors. Also, select applicable safety provisions.
- **Human Subjects:** Human/clinical trials are not permitted under this award mechanism.

• State Legislative Districts:

- State Senate District: Enter the State Senate District of your institution. Use the link provided to find this information using your institutional address.
- State House District: Enter the State House District of your institution. Use the link provided to find this information using your institutional address.

• Cancellation of Applications/Awards by Granting Organization (in past 5 years)

- Select whether the PI is currently eligible to receive federal grant funds. If "No" is selected, please provide the reason in the drop-down text box.
- Select whether the PI had an application or award terminated for cause within the last 5 years. If yes, then select the category of Application or Award. Select the Granting Organization. Enter the Award Title, Award Number, Award Amount, and the Reason for Cancellation. Click the *Add Application/Award* link to include additional applications or awards.

Donations:

- Select whether the PI or any individual listed on the application has made a donation, gift, or grant to CPRIT, the CPRIT Foundation, the Texas Cancer Coalition, or any nonprofit organization/entity established to benefit CPRIT.
- o If yes, then enter the name of the donor, entity name, donation amount, and date of donation. Click the *Add Donation* link to add additional donations.

• CPRIT Priorities Addressed (from Statute or Texas Cancer Plan):

 Choose the CPRIT priority addressed in the application. More than 1 priority may be selected. If Choice 5 is selected, then enter the name of the research sponsor and the sponsor's priority that the application addresses. Review the instructions, and click the appropriate button (Save Application Information as Draft or Finalize Application Information for ASO Approval) to save entered application information.

NOTE: Application information saved "as draft" can be edited at a later time. Application information "finalized for ASO approval" can be edited only after the ASO has reset the application to draft at the request of the PI.

13. TAB 3: COLLABORATORS & CONFLICTS OF INTEREST

Investigators and Submitters: Ensure that biosketches for the PI and Co-PI (if applicable) are uploaded. If the biosketches are missing, they can be uploaded under the My Profile link via that individual's account. This tab cannot be finalized without the biosketch of the PI and Co-PI (if designated).

Please note that the Biosketch that is in My Profile when Tab 3 (Collaborators & COIs) is finalized will be reflected in the final application. Please make sure that you make any updates in the Biosketch before finalizing this Tab. Any changes after this point will be saved in My Profile but will not be copied to the final version of this application.

- Collaborators and Conflicts of Interest (COIs): Enter information for all collaborators and COIs (select the appropriate Role for Application from the drop list). Click the Save as Draft button to save additions.
- Collaborators Listed: Review the list to ensure that all entered collaborators have been successfully added.
- Conflicts of Interest (COIs) Listed: Review the list to ensure that all entered COIs have been successfully added.

When all information is entered, click the *Finalize Collaborators and COIs* button. Note that this tab can be finalized only after Tab 1 (Contacts) has been finalized.

14. TAB 4: REQUIRED DOCUMENTS

NOTE: All documents must be uploaded in PDF format only. The system will not allow upload of documents in other formats or documents that exceed the page limits specified in the RFA. Do NOT password protect documents. Do NOT submit documents that are bound together in a single PDF package.

- Application Abstracts: Abstract and Significance and Layperson's Summary: Enter the Abstract and Significance (5,000 characters) and Layperson's Summary (5,000 characters) of the proposed work. Character limits include letters, spaces, and punctuations. Do NOT use symbols or special characters (eg, Greek letters)—these will not be transmitted correctly. Save the entered information by clicking the *Save Application Abstracts as Draft* button. Information must be saved before any documents are uploaded below or else the Abstract and Significance and/or Layperson's Summary will be lost after the document upload.
- Goals and Objectives: Enter your Goals and Objectives as plain text (1,200 characters per goal and per objective). Goals and objectives will be reviewed during the evaluation of annual progress reports. HTML formatting, tables, charts, and diagrams are not supported. Goals and objectives may be saved as a DRAFT at any time by clicking the *Goals and Objectives as Draft* button. Any unsaved goals and objectives will be lost.
 - At least 1 goal and 1 objective are required. At least 1 objective is required per goal. Up to 5 goals and 5 objectives per goal may be entered.
 - Click the *Add Objective* link to add an additional objective to a goal.
 - Click the *Add Goal* link to add additional goals.
- **Timeline:** Upload Timeline PDF document (1 page). Timeline will be reviewed during the evaluation of annual progress reports.
- **Research and Development Plan:** Upload the Research and Development Plan PDF document (up to 10 pages; see RFA for details).
- Vertebrate Animals and/or Human Biological Samples: Upload the Vertebrate Animals and/or Human Biological Samples PDF document (1 page). If not applicable, upload a page with the following statement: "No vertebrate animals and/or human biological samples will be used."
- Competitive Landscape/Intellectual Property: Upload the Competitive Landscape/Intellectual Property PDF document (up to 5 pages).
- **Publications/References:** Upload the Publications/References PDF document. Journal articles are <u>not allowed</u> under this section.

• **Biographical Sketches of 2 additional Key Personnel:** If desired, up to 2 additional biographical sketches for key personnel may be provided (template is posted under the *Summary* tab). Biosketches must <u>not</u> exceed 5 pages for each individual. If 2 biosketches are being provided, these must be combined into a single file and submitted as a single PDF document (ie, a 10-page document consisting of two 5-page biosketches.)

<u>Attention:</u> Biosketches of the PI and the Co-PI (if designated) are extracted from their respective profiles and are automatically part of the application; these <u>should</u> <u>not</u> be part of this document.

- Current and Pending Support: For all personnel for whom a biosketch is submitted with the application, upload their Current and Pending support (use the template posted under the *Summary* tab). Multiple documents must be combined and submitted as a single PDF document. At a minimum, the current and pending support of the PI and Co-PI (if designated) must be included in this document upload.
- Institutional/Collaborator Support and/or Other Certification: If applicable/desired, upload letters of institutional and/or collaborator support and other certification documents (up to 4 pages). Multiple letters/documents must be combined and submitted as a single PDF document Applicants are strongly advised NOT to submit "appendix material," such as publications, figures, and/or data.
- **Budget Justification:** Upload the Budget Justification PDF document. Provide a <u>brief</u> and concise justification of the budget for the entire proposed period of support for the entire program and for all charge categories: personnel (salaries and fringe benefits), travel, equipment, supplies, consultant charges, contractual (subaward/consortium) charges, research-related subject charges, other expenses (including animal care charges), and indirect charges. <u>Each subaward must itemize project charges for all charge categories.</u> (see also <u>section 15.4</u>).

When all information is entered, click *Finalize Required Documents*.

15. TAB 5: BUDGET

This tab should include only the amount requested from CPRIT; do NOT include the amount of the matching funds.

The budget section is composed of 4 subtabs that must be completed:

- i. Senior/Key Person & Other Personnel
- ii. Detailed Budget for Year 1
- iii. Budget for Entire Proposed Period of Performance
- iv. Budget Justification

All 4 subtabs must be completed to finalize this section. A detailed budget for the first year of the project is required. Applicants may request up to \$1,000,000, inclusive of both direct and indirect charges, over a period of 1 to 3 years. Exceptions to this limit may be requested if extremely well justified (see section 8.3.7 of RFA).

NOTE: Some or all of the following buttons appear on each subtab:

Previous = Move to the previous subtab

Next = Move to the next subtab

Save Budget as Draft = Save entered information

Finalize Budget for ASO Approval = Finalize section

The *Previous* and *Next* buttons allow a user to move between subtabs while retaining entered information for as long as the user is on the *Budget* tab. Information entered on any subtab is NOT saved until the *Save Budget to Draft* button is clicked. Moving to another tab without saving will result in loss of any unsaved changes.

15.1. Senior/Key Person & Other Personnel (use web form provided)

Complete the requested information.

Name: The PI's name is prepopulated. Enter names of other individuals, as necessary.

Additional rows will automatically appear once text is entered into the existing last row.

Role on Project: The PI's role is prepopulated. Enter roles of other individuals as necessary.

Type of Appointment (Months): For each individual listed, enter their appointment type (eg, 6-month, 9-month, 12-month appointment).

(Rev 03/21/16)

Annual Base Salary: For each individual listed, enter his or her institutional base salary.

Effort on Project: For each individual listed, enter percent effort on the project.

Salary Requested: The individual salary cap for CPRIT awards is \$200,000; see section 15.5, Salary Cap. Click *Calc* to automatically calculate the requested salary, or if preferred, the salary requested may be manually entered.

Fringe Benefits: For each individual listed, his/her institutional fringe benefits must be calculated based on their direct Salary Requested. Fringe benefits may not exceed 35% of the salary requested (a warning will be displayed).

15.2. Detailed Budget for Year 1 (use text boxes/web form provided)

Provide the information requested for other direct charges in the first year of the project.

Travel Costs: Include any costs associated with necessary travel. CPRIT funds may be used to send up to 2 people to CPRIT's biennial conference. (The next conference will be held in 2017.)

Equipment (400-character limit): Itemize as necessary. Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. Preapproval is not required; if the project is funded, approval may be requested at that time.

Supplies (800-character limit): Itemize by category, as necessary.

Consultant Charges: State charges for consulting services that may be used during the proposed work.

Contractual (Subaward/Consortium) (400-character limit): Itemize all subaward- and consortium-associated amounts. State direct charges only. Each subaward must be itemized in the Budget Justification subtab by stating project charges for personnel, equipment, supplies, research-related subjects, and other expenses.

Other Expenses (800-character limit): Itemize other project-associated expenses.

Indirect Charges: CPRIT limits indirect charges to a maximum of 5%. *Total Indirect Charges* for Year 1 (line D) should not exceed 5% of the Total Charges for Year 1 (line E). As an example, for a total award of \$100,000, indirect charges may not exceed \$5,000; direct charges would be \$95,000.

Calculate as follows: Total Indirect Charges = (Total Direct Charges/0.95) – Total Direct Charges.

Note for Subawards: Subawards may recover indirect charges of up to the maximum of 5% of the total requested subaward amount. However, because CPRIT awards will be made to the primary institution (which, in turn, will manage the subcontracts), the indirect charges for each subaward are calculated as part of the total amount requested by the primary institution. *Do not include indirect charges in the Contractual (Subaward/Consortium) category.* The appropriate subaward amount—including the allowable indirect charges—will be forwarded to the subaward institution by the primary institution.

15.3. Budget for Entire Proposed Period of Performance

Amounts for *Budget Year 1* will be autopopulated based on the information provided on the previous subtabs; namely, *Senior/Key Person & Other Personnel and Detailed Budget for Year 1*. For each additional year of support requested, enter the budget requested for personnel charges and other applicable direct charges. Fringe benefits may not exceed 35% of the salary (a warning will be displayed). Cost adjustments of up to a 3% annual increase for salary and other categories are permitted for Years 2 and 3. A 3% salary increase for Years 2 and 3 is permitted up to the cap of \$200,000. The salary cap (section 15.5) may be revised every year at CPRIT's discretion.

Enter the indirect charges for each additional year of support requested. *Total Indirect Charges* (line D) should not exceed 5% of the total requested award amount for that year (sum of lines C and D). Calculate as follows: Total Indirect Charges = (Total Direct Charges/0.95) – Total Direct Charges.

15.4. Budget Justification

Provide a <u>brief and concise</u> justification of the budget (15,000-character limit) for the entire proposed period of support for all charge categories: Personnel (salaries and fringe benefits), travel, equipment, supplies, consultant charges, contractual (subaward/consortium) charges, research-related subject charges, other expenses (including animal care charges), and indirect charges. **Each subaward must itemize project charges for all charge categories.** If more than \$1,000,000 in total charges is requested over a period of 1 to 3 years, include a special and clearly labeled section that explains the request.

If you uploaded this document under Tab 4 (Required Documents) (see <u>section 14</u>), you can click on the link directing you to your uploaded file. If you have not uploaded this

CPRIT Instructions for Applicants:

document, please click on the link that will direct you to Tab 4 (Required Documents) where you can upload this file.

15.5. Salary Cap

The salary cap for CPRIT awards in FY 2017 (September 1, 2016, through August 31, 2017) is \$200,000. Thus, the maximum direct salary support an individual can request is up to \$200,000 of their institutional salary based on effort on a project. In other words,

- With 100% effort on the project, individuals with an institutional base salary of less than \$200,000 would request the entire base salary amount.
- With 100% effort on the project, individuals with an institutional base salary of more than \$200,000 would request the salary cap of \$200,000.
- With 50% effort on the project, individuals with an institutional base salary of more than \$200,000 would request \$100,000.

The following table outlines the salary cap guidelines. Institutional fringe benefits should be calculated based on the direct salary support requested.

Base Institutional Salary (full-time calendar appointment)	Effort on Project	Maximum direct salary support that would be requested by the applicant
Less than \$200,000	1-100%	Up to base salary
More than \$200,000 (eg, \$300,000)	100%	\$200,000
More than \$200,000 (eg, \$300,000)	50%	\$100,000

16. TAB 6: FINAL REVIEW & SUBMIT

When Tabs 1 through 5 have been completed and finalized by the applicant, the status of the application is "PENDING ASO APPROVAL." The ASO will then receive email notification to review, approve, and submit the application to CPRIT. Only the ASO is authorized to officially submit the application. The ASO must log in to the system and click the appropriate application ID listed under his or her *My Applications* page. To submit the application, the ASO must enter his/her password and click the *Approve and Submit Application* button. The ASO will then be asked to click the *Continue* button to submit the application. After the application has been

submitted, the status of the application on the *My Applications* page (and also on all tabs of that application) will state "ASO APPROVED AND SUBMITED". The ASO at the PI's organization must submit the application by the submission deadline: **May 19, 2016, 3 PM central time.**

17. PROVIDED TEMPLATES

Applicants must use the provided template to prepare and submit the following documents.

- Current and Pending Support (.doc, .PDF)
- Competitive Landscape/Intellectual Property (.doc, .PDF)
- A template is provided for the biographical sketch, but an NIH biographical sketch may be used if desired.

Templates are posted under the Summary tab and are available in .doc and .PDF format.

18. VERTEBRATE ANIMALS/HUMAN BIOLOGICAL SAMPLES

Whenever vertebrate animals or human biological samples are part of a CPRIT-funded project, a copy of the recipient organization's institutional review board (IRB) and/or Institutional Animal Care and Use Committee (IACUC) approval must be provided to CPRIT before funding can be released. For multiyear projects, annual confirmation of IRB or IACUC approval is required. This information is not required at the time of submission of the application.

19. FORMATTING INSTRUCTIONS

All sections of the application should be written in clear and legible text and must follow the guidelines described below. Applicants are advised to use font sizes, font faces, line spacing, page sizes, and page margins that permit easy readability of the application text. Every attempt should be made to keep files sizes to a minimum (see *Scanning Resolution* below). Applications that do not meet these guidelines are subject to administrative withdrawal.

Formatting guidelines for all submitted CPRIT applications are as follows:

- Language: English.
- **Document Format:** PDF only.
- Font Type/Size: Arial (11 point), Calibri (11 point), or Times New Roman (12 point).
- **Line Spacing:** Single.

- Page Size: 8.5 x 11 inches.
- **Margins:** 0.75 inch, all directions.
- Color and High-Resolution Images: Images, graphs, figures, and other illustrations
 must be submitted as part of the appropriate submitted document. Applicants should
 include text to explain illustrations that may be difficult to interpret when printed in black
 and white.
- Scanning Resolution: Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that just include only text.
- **References:** Applicants should use citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used. An example is included below; however, other citation styles meeting these parameters are also acceptable as long as the journal information is stated. Include URLs of publications referenced in the application.
 - Smith, P.T., Doe, J., White, J.M. (2006). Elaborating on a novel mechanism for cancer progression. *Journal of Cancer Research*. 135, 45-67.
- Internet URLs: Applicants are encouraged to provide the URLs of publications referenced in the application; however, applicants should not include URLs directing reviewers to websites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer.
- Supplemental ("Appendix") Material: Permitted only if certification documents and/or clinical trial protocols are vital to the evaluation of the proposed research study.
 Applicants are strongly advised not to submit publications, figures, and/or data.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

20. CONTACT INFORMATION

20.1. HelpDesk

HelpDesk support is available for technical questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

20.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

APPENDIX 1: DESCRIPTION OF RESEARCH AREAS

In Tab 2 (Application Information/Application Classification) the applicant is required to select a research area that best describes the proposed work. Descriptions of research areas are as follows:

- Cancer biology: Research on the biology of how cancer starts and progresses as well as normal biology relevant to these processes. Examples include oncogenes and suppressor genes, epigenetics, DNA repair, growth factors, signaling pathways, cancer immunology, microenvironment, tumor progression, and metastasis.
- Cancer control, survivorship, and outcomes research: Research in this category covers a broad range of areas including patient care and pain management, cancer surveillance, cancer disparities research, quality of life for patients with cancer and their families, identification and reduction of late effects of cancer treatment, education and communications that reduce cancer risk, health services research, and attitudes and belief systems that affect cancer control.
- Childhood and adolescent cancer
- Computational biology and analytic methods
- Early detection, diagnosis, and prognosis: Identification and testing cancer markers and imaging methods detecting and/or diagnosing cancer as well as predicting the outcome or chance of recurrence. Examples include discovery of markers and/or technologies for use in cancer detection and diagnosis and/or prognosis, animal trials and clinical human trials, tumor response to therapy, risk assessment, screening methods, informatics and informatics networks, and biostatistics.
- **Etiology:** Research on the causes of cancer—genetic, environmental, and lifestyle factors and their interactions. Examples include environmental chemicals, hormone-disrupting agents, gene-environment interactions, microbial agents, radiation exposure, and genetic polymorphisms that affect carcinogen metabolism.
- Prevention: Identification of interventions that reduce cancer risk. Examples include
 chemoprevention, vaccines to prevent cancer, behavioral modifications that reduce
 cancer risk, studies on energy balance and dietary factors associated with cancer risk, and
 identification of cancer risk factors.

APPENDIX 2: PROGRAM FOCUS - DEFINITIONS OF CANCER RESEARCH TYPES

In Tab 2 (Application Information/Application Classification), the applicant is required to select a program focus that best describes the proposed cancer research type. Descriptions of cancer research types are as follows*:

- **Basic Research** results in the acquisition of new knowledge and elucidates fundamental mechanisms in biology.
- Translational Research involves the application of discoveries from basic research to
 practical problems associated with cancer as well as research on how to improve best
 practices in the community.
- Clinical Research involves studies with human subjects and includes patient-oriented research on mechanisms of disease, therapy, and development of new technologies as well as epidemiologic and behavioral studies and outcomes and health services research.

*Taken from, Rubio et al, "Defining Translational Research: Implications for Training," Academic Medicine. 85:470–475, 2010.